

## REMARKS

The Office Action of August 12, 2005 has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested in view of the amendments and remarks presented in this response.

Claims 1-2, 4-13 and 15-28 are pending in this application. Claims 9-10 and 16-24 were Withdrawn. Claims 1, 11, 12, 15, 25, and 28 have been amended as discussed below.

### **U.S. Application Serial No. 60/259,348**

Provisional application Serial No. 60/259,348 discloses *inter alia* biomedical implants of thermoplastic materials infiltrated with an osteoinductive composite for load-bearing tissue engineering applications. The provisional application also teaches that bone degrades the osteoinductive composite parts and fills the space with bone. The thermoplastic materials degrade much more slowly and are replaced in a second stage after bone has grown into the implant. (*See, e.g.*, p. 4, lines 14-21). Additionally, the provisional application discloses that the thermoplastic materials may be polymethylmethacrylate (PMMA), polybutyleneterephthalate (PBT), and polyetheretherketone (PEEK). (*See, e.g.*, p. 2, lines 13-14). The osteoinductive compositions can include polylactic acid, polycaprolactone, calcium phosphate and combinations thereof. (*See, e.g.*, p. 9, line 22 – p. 10, line 2).

### **U.S. Application Serial No. 10/038,398**

Independent claims 1, 11 and 25, as amended, relate to a biocompatible implant of polybutyleneterephthalate (PBT), polyethyletherketone (PEEK) and combinations thereof and to a method of repairing or replacing tissue utilizing such an implant. The implants have a pore size of about 150 to about 400  $\mu\text{m}$  (claim 1) and of about 100 to about 2400  $\mu\text{m}$  (claims 11 and 25), and porosity between about 50% to about 60% (claim 1) and between about 25% to about 70% by volume (claims 11 and 25). PBT and PEEK implants have enhanced mechanical strength. This is demonstrated, for example, by Example 3 of the application in which it is illustrated that the strength and modulus for a PMMA sample was significantly lower than for a PBT sample. (*See* p. 25, lines 21-28, and FIGS. 7 and 8). The implants also may include composition for enhancing the rate of bone growth including polylactic acid, polyglycolic acid, polylactic acid-polyglycolic acid copolymer, polycaprolactone, a calcium source and combinations thereof. The implant provides load-bearing support during growth of new bone structure and enhances bone growth.

### **Claim Rejection Under 35 USC §112**

Claims 25-28 stand rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because claim 25 recites the limitation “a ceramic composition selected from the group consisting of polylactic acid, polyglycolic acid, polylactic acid-polyglycolic acid copolymer, polycaprolactone, and combinations thereof” although none of the recited compositions are ceramic compositions. Claims 11, 12, 15, 25, and 28 have been amended to clarify that merely ceramic compositions were intended to be claimed but also polymer compositions and polymer-ceramic compositions. Reconsideration and withdrawal of this rejection is respectfully requested.

### **Claim Rejections Under 35 USC §103**

As an initial matter, the Office Action states that the priority date of the present invention is January 2, 2002, the filing date of the present application. The provisional application complies with the requirements of 35 USC § 112, and the present application properly claims the benefit of the provisional application in the specification of the present application. Thus, Applicants respectfully submit that the application should be afforded the benefit of the priority date of the provisional application, *i.e.*, January 2, 2001.

With respect to the pending claims, Applicants also respectfully submit that the claims should be entitled to the filing date of the provisional application. “Polyetheretherketone” and “polyethyletherketone” are not different compounds. Both spellings are used by persons of skill in the art to refer to the same compound, which also is commonly abbreviated as “PEEK.” (*See, e.g.*, U.S. Patent Nos. 6,519,824 and 6,069,223 and Luther et al., *J. Environ. Monit.*, 2001, 3, 61-66, attached). Thus, Applicants submit that the priority date of the pending claims is January 2, 2001, and Walish et al. is not prior art under 35 USC 102(b). Applicants are prepared to submit an affidavit pursuant to 37 CFR 1.131 to establish invention prior to the effective date of the Walish et al. publication, which was authored in part by the inventors of the present application.

Claims 1-2 and 4-7 stand rejected under 35 USC §103(a) for being unpatentable over Walish, et al., (Symposium Y) in view of DeBruijn, et al. (U.S. Patent No. 6,228,117). Claims 11-13 and 15 stand rejected under 35 USC §103(a) for being unpatentable over Walish, et al., (Symposium Y) in view of DeBruijn, et al. (U.S. Patent No. 6,228,117) in further view of

Vyakarnam, et al. (U.S. Patent No. 6,534,084). Claims 6, 8 and 25-28 stand rejected under 35 USC §103(a) for being unpatentable over Walish, et al., (Symposium Y) in view of DeBruijn, et al. (U.S. Patent No. 6,228,117) in further view of Kumar (U.S. Publication No. 2002/0127391).

Walish et al. do not disclose the invention as presently claimed. Walish et al. merely disclose porous implants made from slowly-degradable polyesters that are impregnated with a biodegradable polyester/hydroxyapatite blend. The implant materials are referred to as combining a strong support material with a biodegradable composite. The Walish et al. abstract does not disclose any additional details regarding the properties or characteristics of the implants. Importantly, Walish et al. do not disclose that the implant materials include PBT and/or PEEK, or that the materials have any specific pore size or porosity, as presently claimed. Walish et al. also do not disclose that the implants also include compositions for enhancing the rate of bone growth including polylactic acid, polyglycolic acid, polylactic acid-polyglycolic acid copolymer, polycaprolactone, a calcium source and combinations thereof.

DeBruijn et al., Vyakarnam et al. and Kumar do not suggest the implants as claimed and do not provide any teachings to cure the deficiencies of Walish et al. DeBruijn et al. disclose a device for facilitating cell growth *in vitro* prior to implantation of the device. The device is made of a thermoplastic polymer and provides one example of a PEO/PBT copolymer. Vyakarnam et al. disclose an interconnected, open cell porous foam. Kumar discloses a coating for a substrate, such as a plate, where the coating includes a ceramic in a resorbable polymer binder. The ceramic preferably is a phosphate, carbonate, bicarbonate or sulfate, and the polymer is composed of lactic acid, glycolic acid, amides, anhydrides, orthoesters, and dioxanones.

Accordingly, Walish et al., DeBruijn et al., Vyakarnam et al. and Kumar, either alone or in combination, do not disclose, teach or suggest the invention of independent claims 1, 11, and 25, as well as any of the dependent claims, and the claims pending in the present application are not obvious. In view of the above, reconsideration and allowance of the pending claims are respectfully requested.

### CONCLUSION

In view of the above amendments and remarks, prompt reconsideration and full allowance of the claims pending in the subject application are respectfully requested. All rejections having been addressed, Applicants respectfully submit that the instant application is in condition for allowance and respectfully solicit prompt notification of the same.


The Commissioner is authorized to debit or credit our Deposit Account No. 19-0733 for any fees due in connection with the filing of this response.

If the Examiner should have any questions, the Examiner is invited to contact the undersigned at the number set forth below.

Date: February 13, 2006

Respectfully submitted,

By: \_\_\_\_\_



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